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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
Paul CLAYTON)
Serial No.: 10/014,488) Group Art Unit: 1617
Filed: December 14, 2001) Examiner: J. Kim
For: HEALTH PROMOTING)
COMPOSITIONS OF)
COMPOUNDS)

Assistant Commissioner for Patents
Washington, DC 20231

RESPONSE UNDER 37 C.F.R. 1.111

Sir:

In response to the Office Action dated October 22, 2002, Applicant submits the following remarks. In a separate petition, Applicant has requested and paid for a one month extension of time. Thus, this response is timely filed.

FORMAL MATTERS

The present Office Action did not include a copy of PTO form 1449 indicating that the references submitted with the Information Disclosure Statement on December 14, 2001, have been considered. The Examiner is requested to provide an initialed copy of the 1449 form submitted on December 14, 2001.

REMARKS

The Office rejects claims 1-33 as allegedly obvious over Kosbab (WO 98/33494) ("Kosbab") in view of Gilles *et al.* (U.S. Patent No. 6,248,375 B1) ("Gilles"). Office Action, page 2. According to the Office, Kosbab describes a composition comprising the active agents and their respective dosage amounts that are recited in claims 1, 6,

11, 13, 17, 22, and 29. *Id.* The Office acknowledges that Kosbab does not describe a composition containing FOS or insulin. *Id.*, at page 3. However, the Office states that one of skill in the art would be motivated to employ FOS and insulin in view of Gilles because Gilles:

teach that FOS in diabetic composition is preferential energy source to beneficial bacteria in the diabetic nutritional composition. Therefore, the skilled artisan would be motivated to combine well known insulin (... col. 1, lines 22-25, Gilles et al.) and any other active agents taught by Gilles composition including FOS to Kosbab's composition with a reasonable expectation of success....

Id.

Applicant respectfully traverses this rejection because the Office has not established a proper obviousness rejection. A *prima facie* case of obviousness requires some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or combine their teachings. There must also be a reasonable expectation of success. M.P.E.P. § 2143. Furthermore, the teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in the Applicant's disclosure. *Id.*; see also *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991). The mere fact that references can be combined or modified does not render the combination obvious unless the references themselves suggest the desirability of the combination.

First, Applicant contends that there is no motivation to combine the references in the manner proposed by the Office. The claimed invention recites compositions containing multiple compounds (e.g., claim 1 recites at least 29 compounds) at specific dosages. Each compound in claim 1, with the exception of the mixed Omega acids,

FINNEGAN
ENDERSON
FARABOW
GARRETT &
DUNNER LLP

1300 I Street, NW
Washington, DC 20005
202.408.4000
Fax 202.408.4400
www.finnegan.com

FOS and insulin, is given in a specific amount that can vary by no more than 15% (w/w) above or below the specified amount. For example, instant claim 1 recites four components that Kosbab describes as "antioxidant carotenoids" in Table 3. In instant claim 1, each of these components is provided in specific dosage amounts plus or minus 15% w/w (beta-carotene is 10 mg, lutein is 6 mg, lycopene is 5 mg and zeaxanthin is 100 mcg).

Kosbab, on the other hand, describes nutrient and therapeutic formulations that contain from four to about fifty components in extremely broad dosage ranges. For the antioxidant carotenoids described above, Kosbab describes the concentrations as 10-100,000 IU (beta-carotene) and 1-300 mg for each of the remaining three compounds. See Table 3. There is no suggestion in Kosbab that would lead the skilled artisan to select the specific dosages of the claimed invention from the extremely broad ranges described by the prior art.

Gilles does not account for these deficiencies. Gilles describes bagels, biscuits, cookies and other solid goods containing an alternative source of carbohydrates that can be incorporated into a diabetic's diet. In addition to FOS, Gilles also lists biotin and niacin in a long laundry list of vitamins and minerals that would be useful in a solid nutritional matrix. Gilles, Col. 11, lines 1-11. However, the amounts of these vitamins and minerals in the Gilles baked goods are present in much lower amounts than those found in the claimed invention. Gilles, Col. 14, lines 26-33 and Col. 15, lines 56-63.

And there is no suggestion in Gilles that would lead one of skill in the art to manipulate these amounts to arrive at the specific dosages of the claimed invention.

FINNEGAN
HENDERSON
FARABOW
GARRETT &
DUNNER LLP

1300 I Street, NW
Washington, DC 20005
202.408.4000
Fax 202.408.4400
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Also, there is no motivation to combine the medicinal formulations described by Kosbab with the bagels, biscuits, cookies (and other solid goods) described by Gilles. These are completely different utilities. As the Office notes, Gilles describes FOS in baked goods as a preferred indigestible polysaccharide because of its beneficial effect on intestinal flora. While this may be an important consideration in designing foods, it does not mean that such a benefit is also realized when FOS is used in medicinal formulations. In fact, it may be undesirable to add carbohydrate sources (*i.e.*, extra calories) to medicines. Consistent with this, Kosbab does not describe a carbohydrate source for use in his therapeutic and nutritional compounds. The only carbohydrate mentioned by Kosbab is used in the formation of topical ointments for wound healing (*e.g.*, honey). Kosbab, page 10, lines 10-18. Thus, the skilled artisan would not be motivated to pick FOS from Gilles' baked goods to use as a carbohydrate source in Kosbab's medicines. Nor would there be any reasonable expectation of success in doing so. And the Office has not provided evidentiary support showing a motivation to select the specific compounds at the specific dosages for combination into the claimed composition. *See In re Grose*, 592 F.2d 1161, 201 U.S.P.Q. 57 (C.C.P.A. 1979).

In addition, even if the combination proposed by the Office were to be made, it does not teach all of the elements of the claims. The Office contends that "the difference between the primary reference [Kosbab] and Applicant's claimed invention is absence of FOS and insulin." Office Action, page 3. In order to make this statement, the Office relies on the diverse compounds listed by Kosbab on pages 47-51 (Table 3 listing the preferred broad ranges for all of the compounds used in the various Kosbab compositions). However, it is also true that several other active agents required by the

FINNEGAN
HENDERSON
FARABOW
GARRETT &
DUNNER LLP

1300 I Street, NW
Washington, DC 20005
202.408.4000
Fax 202.408.4400
www.finnegan.com

claimed invention are missing from the particular compositions described by Kosbab, and are not found among the myriad of compounds listed in Tables 2 and 3. These non-disclosed compounds include omega 6 fatty acid, biotin, and curcuminoids (see claim 13). Additionally, Applicant notes that Kosbab actually teaches away from the use of niacin (or nicotinamide) in his diabetic formulations. See Kosbab, page 9, line 32. Moreover, like Kosbab, Gilles does not describe the use of omega 6 fatty acid, or curcuminoids.

Kosbab, moreover, does not teach that all of the compounds in Table 3 may be combined with any of the other compounds listed in that table. Quite to the contrary, Kosbab teaches very specific combinations of compounds (see Kosbab, pages 4-18). Thus, the Office's attempt to derive the presently claimed composition by conveniently mixing and matching the compounds listed in Table 3 (and elsewhere in Kosbab) with compounds found in Gilles into a single composition is contrary to Kosbab's own teachings. Here, the Office is attempting to create something that the cited art does not teach, and using Applicant's invention as a roadmap for doing so. This is impermissible. The combination of Gilles and Kosbab simply does not teach every element of the claims.

More significantly, even if, *arguendo*, one of skill in the art could pick and choose among the compounds listed in Kosbab and Gilles, it would not result in a composition containing insulin. As noted by the Office, Kosbab does not disclose insulin. Office Action, page 3. To account for this deficiency, the Office relies on Gilles, Col. 1, lines 22-25. This sole reference to insulin in Gilles states only what is commonly known -- that the primary treatment for glucose intolerance is diet and in some cases,

medications such as insulin or oral hypoglycemic agents. Gilles then goes on to describe his invention which relates to diet alone. Gilles never makes use of, or suggests the use of, insulin in his invention. Consequently, one of skill in the art, utilizing the teachings of Gilles, would not be motivated to select insulin as a component in any formulation.

Kosbab does not provide the missing teaching. While adding many kinds of medicaments to his formulations, such as amylin, antibiotics, hormones, aspirin and NSAIDS, Kosbab does not teach or suggest the addition of insulin. The fact that Kosbab entertained the addition of many medicaments to his formulations, but did not choose to add insulin, could be read by one skilled in the art as a teaching away from the composition comprising insulin. There is simply no teaching or suggestion in the prior art to add insulin to the formulations of Kosbab or of Gilles. Again, the combination of cited prior art fails to teach all of the elements of the claims.

In summary, the prior art references cited by the Office, either alone or in combination, do not provide any motivation to pick and choose the particular components and specific dosages recited in the present claims. The Office has simply used Applicant's specification as a blueprint to pick and choose elements from the prior art in order to recreate the claimed invention. At best, these two patents suggest that the claimed invention might be "obvious to try," which is not a legitimate test of patentability. *In re Fine*, 837 F.2d 1071, 1075, 5 U.S.P.Q.2d 1596, 1599 (Fed. Cir. 1988) (citations omitted). Thus, Applicant contends that the Office has failed to establish a *prima facie* case of obviousness and respectfully requests that the rejection be withdrawn.

FINNEGAN
HENDERSON
FARABOW
GARRETT &
DUNNER LLP

1300 I Street, NW
Washington, DC 20005
202.408.4000
Fax 202.408.4400
www.finnegan.com

CONCLUSION

In view of the foregoing remarks, Applicant respectfully requests the reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: February 21, 2003

By: JPD Reg. No. 46249

For: Carol P. Einaudi
Reg. No. 32,220

FINNEGAN
HENDERSON
FARABOW
GARRETT &
DUNNER LLP

1300 I Street, NW
Washington, DC 20005
202.408.4000
Fax 202.408.4400
www.finnegan.com